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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

MILLER, CHERYL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3738

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/716,146 | Applicant(s) BOYLE, CHRISTOPHER T. 6 | |
| | Examiner Cheryl Miller | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,20 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,20 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>attachments 1-5</u> . |

DETAILED ACTION

Response to Arguments

In view of the Appeal Brief filed on January 7, 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Applicant's arguments with respect to the rejection of claims 16, 20, and 26-28 over the Brown et al. reference (US 6,071,305) have been considered however are found non-persuasive. Applicant has again argued that Brown does not anticipate structural elements having separate layers, specifically, that Brown does not disclose a void layer between two layers, and argues further that Brown fails to disclose a first region having a base layer and a second region having a second layer covering the base layer, the second region further comprising a layer of void space intermediate the base and second layers and enclosed therebetween. The examiner disagrees. Brown has disclosed many embodiments having the layers as claimed. One embodiment is shown in figure 5 (see attachment 1), wherein one layer (seen in yellow) may be considered element 12'' and another layer (seen in red) may be considered 34 (it is noted to the

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applicant, that although the structural elements are metal, the “layers” are not required by the claim to be metal), the void layer 20 being therebetween. Another embodiment is shown in figure 7 (see attachment 2), wherein one layer (seen in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (seen in green) or even 49 (seen in red), the void layer 20 therebetween. Also in figure 7 (see attachment 3), one layer (seen in yellow) may be considered the right side of outer perimeter, and a second layer (seen in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween. Another embodiment in figure 8, (see attachment 3), shows a layer to be the outer perimeter (shown in yellow) and a second layer (shown in green) and void 20 therebetween. Figure 10 and 12 also show similar separate discrete layers (as applicant has argued are not present and is discussed below). The term “layer” is defined broadly by “a single thickness overlying a surface”, and it is noted to the applicant a single thickness is not necessarily a constant thickness. Even so, Brown has shown such thicknesses in all of Brown’s figures, and a square cavity in a square cross sectional element (as disclosed by Brown) would provide single and even constant thicknesses anyhow. The applicant has also argued that Brown does not disclose layers that are separate and discrete, but instead are unitary. The examiners position is that the applicant themselves does not have separate discrete layers. The applicant deposits layer upon layer during the fabrication process, in order to make a unitary end product. The unitary end product having the same structure as Brown. Brown may not use a deposition process to form the final structure, and may not deposit layer upon layer of material, Brown does however have an end product the same as the applicants. Whether Brown uses laser treatment or

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deposition to arrive at the final device, the same end device results. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227, USPQ 964, 966 (Fed. Cir. 1985), see MPEP 2113. That is, in the scope that the applicant has described, "layer" in their specification, Brown in this case, also has such layers, Brown's elements may be described at a unitary structure made up of many layers. One could call any particular thickness within Brown's element to be a "layer", see attachment 4 and attachment 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Referring to claim 16, applicant has claimed "a first region comprising a base *layer* and a second region comprising a second *layer* covering the base *layer*, the second region further comprising a *layer* of void space..." emphasis added. Nowhere in the applicant's specification or in the drawings, has the applicant disclosed or pointed to in the drawings,

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structural “layers” in the structural elements. The specification and drawing seem to instead disclose luminal and abluminal *surfaces*, and a void *cavity*. It is unclear to the examiner what the claimed “layer” is, what form it is in, what structural element in the drawing represents it. The only reference to a “layer” in the specification, is on page 11, lines 8-12, in which the method of production is disclosed. During production, layers of material are deposited upon one another to form the final device. The term layer, being used to only describe the manner in which the material is deposited during fabrication. Therefore, the final device does not have separate, discrete layers as the applicant has argued in the appeal brief, and has claimed, but instead, deposits multiple layers during fabrication in order to make a unitary one piece structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (US 6,071,305, cited in previous office action). The examiner’s interpretation of the “layers” in the Brown reference is also pointed out in Attachments 1-5. Referring to claim 16, Brown discloses an endoluminal stent (11, 40”, 111) comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is, although Brown has shown a helical stent made of one structural element in

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fig. 1, Brown also discloses use of a stent with multiple structural elements, wires/fibers/filaments, col.7, lines 34-40; or element seen in cross section fig.12 and disclosed in col.11, lines 50-61; or elements 112 in fig.18) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in fig.3-12 as the cross-sectional dimension), wherein the structural elements (member 12, or member shown in fig.12) are comprised of a first region comprising a base layer and a second region comprising a second layer covering the base layer, the second region further comprising a layer of void space (20) intermediate the base and second layers and enclosed therebetween (see arguments above and attachments 1-5) and a plurality of pores (pores may be openings 22, 28, 54; col.6, lines 12-21 or alternatively pores may be pores in the porous stent material col.10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Referring to claim 20, Brown discloses a degradable plug (biodegradable matrix 27 extending into pore, as is seen in figs.3, 7, 9, and 12, see col.8 line 61-67 and col.9, lines 1-7; or membrane 34, 50, see col.9, lines 12-21, which is disclosed to made of the same materials are the biodegradable matrix, col.9, lines 1-5, 17-21) residing within the plurality of pores.

Referring to claim 26, Brown discloses a stent (10, 40'') having structural elements (member 12 in fig.1-10 or member shown in fig.12) comprising a material selected from the group claimed (col.7, lines 12-19).

Referring to claim 27, Brown discloses a bioactive or active agent (23) selected from the group claimed (col.5, lines 1-27).

Referring to claim 28, Brown discloses a void space (20 or channel in fig.12) comprising a plurality of independent internal cavities along the length of the structural elements (a plurality of cavities are shown in fig.9, 10, and 18; and cavities are shown to be intermittent in fig.18).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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